



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,316	12/01/2005	Roger Victor Bonnert	06275-450US1	4511
26164 7590 11/12/2008 FISH & RICHARDSON P.C. P.O BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER MOORE, SUSANNA	
			ART UNIT 1624	PAPER NUMBER
			NOTIFICATION DATE 11/12/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/528,316	Applicant(s) BONNERT, ROGER VICTOR	
	Examiner SUSANNA MOORE	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/11/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/11/08,9/11/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/11/2008 has been entered.

Response to Arguments

Applicant's argument, see Remarks, filed 12/27/2007, with respect to the rejection(s) of claim(s) 1 and 9 have been fully considered.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 9/11/2008 was filed after the mailing date of the RCE (request for continued examination) on 9/11/2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

The disclosure is objected to because of the following informalities: the Specification should be written as outlined below.

Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

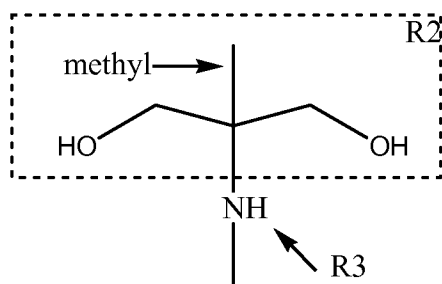
- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 103

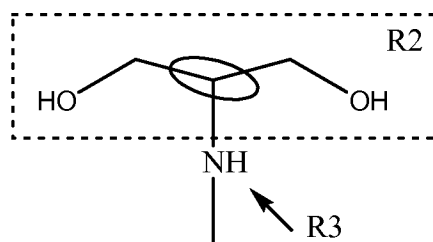
The rejection of claims 1 and 9 under 35 U.S.C. 103(a) as being obvious over Willis et. al. (WO 01/25242, US equivalent is 6790850) in view of Berge et. al. (J. of Pharm. Sciences, 1977, pages 1-19) is **withdrawn** based on the Remarks and declaration submitted by Thomas McNally. The declaration compares the following compounds 5-[(2,3-

Art Unit: 1624

difluorophenyl)methyl]thio]-7-[[2-hydroxy-1-(hydroxymethyl)propyl]amino]thiazolo[4,5-d]pyrimidin-2(3H)-one as the monosodium salt and 5-[[[(2,3-difluorophenyl)methyl]thio]-7-[[2-hydroxy-1-(hydroxymethyl)ethyl]amino]thiazolo[4,5-d]pyrimidin-2(3H)-one as the monosodium salt, see page 3, point 15 and page 14, example 2, of the declaration. The difference between the instant invention and the reference is a methyl substituent as illustrated below.



R2 and R3 with attached nitrogen of the current case



R2 and R3 with the attached nitrogen of the co-pending case

The provisional rejection of claims 1 and 9 under 35 U.S.C. 103(a) as being obvious over copending Application No. 10863995 which has a common assignee with the instant application is **withdrawn** since this case is a related case with the same disclosure as the '850 patent cited above

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible

harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

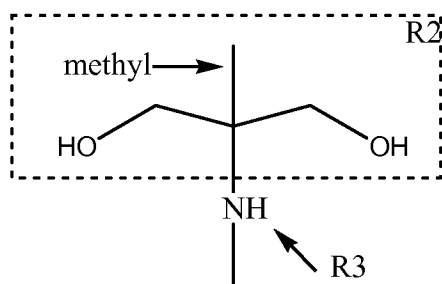
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

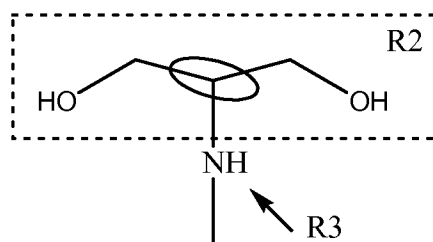
The rejection of claims 1 and 9 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,790,850 is **withdrawn** based on the Remarks and declaration submitted by Thomas McNally. The declaration compares the following compounds 5-[[2,3-difluorophenyl)methyl]thio]-7-[[2-hydroxy-1-(hydroxymethyl)propyl]amino]thiazolo[4,5-d]pyrimidin-2(3H)-one as the monosodium salt and

Art Unit: 1624

5-[[[(2,3-difluorophenyl)methyl]thio]-7-[[2-hydroxy-1-(hydroxymethyl)ethyl]amino]thiazolo[4,5-d]pyrimidin-2(3H)-one as the monosodium salt, see page 3, point 15 and page 14, example 2, of the declaration. The difference between the instant invention and the reference is a methyl substituent as illustrated below.



R2 and R3 with attached nitrogen of the current case

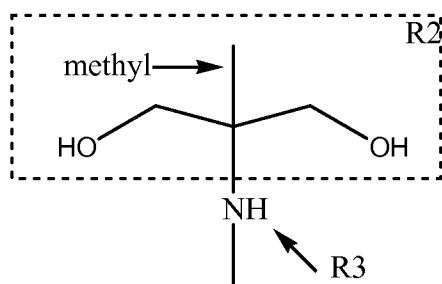


R2 and R3 with the attached nitrogen of the co-pending case

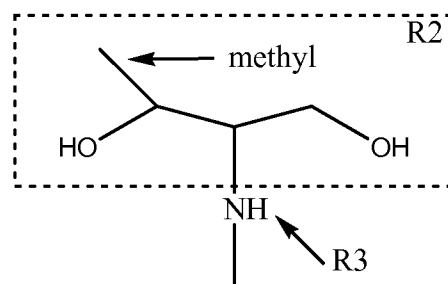
The rejection of claims 1 and 9 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20-26 of copending Application No. 10/863995 is **withdrawn** based on the Remarks and declaration submitted by Thomas McNally.

Claims 1 and 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 9 of copending Application No. 10528270. Although the conflicting claims are not identical, they are not patentably distinct from each other because the specie found in claim 1 of formula (I) of the co-pending application, 5-[[[(2,3-difluorophenyl)methyl]thio]-7-[2-hydroxy-(1-hydroxymethyl))propyl]amino]thiazolo

[4,5-d]pyrimidin-2(3 H)-one, is a positional isomer of the specie found in claim 1 of the instant application. The difference between the two compounds is the location of the methyl group illustrated below.



R2 and R3 with attached nitrogen of the current case



R2 and R3 with the attached nitrogen of the co-pending case

The MPEP 2144.09 states “Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) ... are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant traverses the above rejection by stating the instant invention is claiming particularly the *monosodium salt* of 5-[[2,3- difluorophenyl)methyl]thio]-7-[[2-hydroxy- 1-(hydroxymethyl)- 1- methylethyl]amino]thiazolo[4,5-d]pyrimidin-2(3H)-one. Moreover, claim 1 of the '270 application recites a particular stereoisomer having 2 stereocenters in the S

Art Unit: 1624

configuration, namely 5- [[(2,3-difluorophenyl)methyl]thio]-7- {(1S,2S)-2-hydroxy- 1-(hydroxymethyl)- propyl]amino}thiazolo[4,5-d]pyrimidin-2(3H)-one, rather than a compound of undesigned stereochemistry as referred to by the Examiner in the rejection. “Applicant goes to recite, “In fact, Berge states that sodium is the most predominant cation "because of simple availability and physiological reasons." Berge is silent as to whether or not sodium salts would be expected to achieve better results than a free compound or other salts.”

This is not found persuasive. As mentioned previously, claim 1 of the copending Application claims pharmaceutically acceptable salts, see claim 1 and see page 4, line 20. Furthermore, Berge et. al. teaches sodium as a pharmaceutically acceptable salt. The fact that Berge points to sodium in Table 1, which was the preferred salt (68%) used through the year 1974, is sufficient for one of ordinary skill in the art to use sodium as a starting point or as a lead compound. Moreover, a particular stereoisomer is close enough structurally to render a different stereoisomer obvious. The M.P.E.P. states (2144.08) In fact, similar properties may normally be presumed when compounds are very close in structure. *Dillon*, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also *In re Grabiak*, 769 F.2d 729, 731, 226 USPQ 870, 871 (Fed. Cir. 1985) (“When chemical compounds have very close’ structural similarities and similar utilities, without more a prima facie case may be made.”). Thus, evidence of similar properties or evidence of any useful properties disclosed in the prior art that would be expected to be shared by the claimed invention weighs in favor of a conclusion that the claimed invention would have been obvious. *Dillon*, 919 F.2d at 697-98, 16 USPQ2d at 1905; *In re Wilder*, 563 F.2d 457, 461, 195 USPQ 426, 430 (CCPA 1977); *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

To overcome the rejection, Applicant should compare the monosodium salt of the claimed compound in the '316 Application to show unexpected results since this is the comparison being made in this rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/
Examiner, Art Unit 1624

/Brenda L. Coleman/
Primary Examiner, Art Unit 1624

Application/Control Number: 10/528,316
Art Unit: 1624

Page 10